

IN THE DRAWINGS

Applicants submits formal drawings herewith.

REMARKS

Applicants have received the Office Action dated September 20, 2004, and the references cited therewith.

In this response, claims 1, 4, 9, 10, 13, 18, and 20 are amended. Claims 24-33 are added and claims 7, 12, 21, and 22 are cancelled without prejudice or disclaimer. Claims 1-6 and 8-11, 13-20, and 23-33 are now pending in this application. The amendments to the claims are supported in the specification and drawings as originally filed. No new matter has been added.

§102 Rejection of the Claims

Claims 1-6, 8-19 and 21-23 were rejected under 35 USC § 102(b) as being anticipated by Altman et al. (U.S. Patent No. 6,358,247). Applicants respectfully traverse these rejections.

“For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference.” *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). Altman does not show each element of the claims.

Claim 1

Applicants respectfully submit that Altman does not show each element of claim 1. For example, Applicants cannot find in Altman an “active fixation assembly having one or more pockets therein” as required by claim 1. Reconsideration and withdrawal of the rejection of claim 1 is respectfully requested.

Claims 2-6 and 8-9

Applicants respectfully submit that claims 2-6 and 8-9 are allowable at least because they depend from an allowable independent claim. MPEP § 2143.03. As described above, Applicants cannot find in Altman an “active fixation assembly having one or more pockets therein” as required by claim 1, from which claims 2-6 and 8-9 depend.

In addition, Applicants cannot find other limitations of claims 2-6 and 8-9 in Altman. For example, Applicants are unable to find in Altman “a drug eluting substance disposed within one or more pockets” as required by claim 4. Applicants are also unable to find in Altman an “active fixation assembly includes a hypotube having a lumen therein” in combination with the

other elements required by claim 5. Reconsideration and withdrawal of the rejection of claims 2-6 and 8-9 is respectfully requested.

Claim 10

Applicants respectfully submit that Altman does not show each element of claim 10. For example, Applicants cannot find in Altman “a plug disposed within the at least one passage” in combination with the other elements required by claim 10. Reconsideration and withdrawal of the rejection of claim 10 is respectfully requested.

Claims 11 and 13-17

Applicants respectfully submit that claims 11 and 13-17 are allowable at least because they depend from an allowable independent claim. MPEP § 2143.03. As described above, Applicants cannot find in Altman “a plug disposed within the at least one passage” in combination with the other elements required by claim 10, from which claims 11 and 13-17 depend. Reconsideration and withdrawal of the rejection of claims 11 and 13-17 is respectfully requested.

Claim 18

Applicants respectfully submit that Altman does not disclose each element of claim 18. For example, Applicants cannot find in Altman “forming at least one recess in the helix by removing material from an outer surface of the fixation helix” in combination with the other elements required by claim 18. Reconsideration and withdrawal of the rejection of claim 18 is respectfully requested.

Claims 19 and 23

Applicants respectfully submit that claims 19 and 23 are allowable at least because they depend from an allowable independent claim. MPEP § 2143.03. As described above, Applicants cannot find in Altman “forming at least one recess in the helix by removing material from an outer surface of the fixation helix” as required by claim 18, from which claims 19 and 23 depend.

In addition, Applicants cannot find other limitations of claims 19 and 23 in Altman. For example, Applicants are also unable to find in Altman “disposing a drug eluting substance within the at least one recess within the helix” in combination with the other elements required by claim 19. Reconsideration and withdrawal of the rejection of claims 19 and 23 is respectfully requested.

§103 Rejection of the Claims

Claim 7

Claim 7 was rejected under 35 USC § 103(a) as being unpatentable over Altman et al. (U.S. Patent No. 6,358,247). Applicants respectfully traverse this rejection. New independent claim 26 incorporates the limitations of claim 7. Claim 7 is cancelled without prejudice.

To support a rejection under § 103, the references when combined must teach or suggest all the claim elements. MPEP § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Applicants respectfully submit that Altman does not teach or suggest all elements of prior claim 7 or present claim 26. For example, Applicants cannot find in Altman “least one of the one or more cavities extends from a first side of the active fixation assembly to a second side of the active fixation assembly, forming a passage therethrough,” as recited in claim 26.

In addition, the Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). The Office Action stated “To make the cavities of Altman extend from one side of the helix to the other would have been obvious since such would allow for a greater flow of drugs to the tissue at the required depth of penetration.” (Office Action, p. 3.) Applicants note that the Office Action fails to provide full objective support for this assertion, as required by Lee. The statement is therefore based at least in part on subjective belief. Applicants timely traverse the assertion under § 2144 and request that a reference supporting the assertion be provided. Applicants also request an affidavit pursuant to § 2144.03 to support any facts within the personal knowledge of the examiner that are relied upon in making the rejection. Applicants submit that a legally sufficient motivation to modify Altman to provide the claimed device has not been established.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 20

Claim 20 was rejected under 35 USC § 103(a) as being unpatentable over Altman et al. (U.S. Patent No. 6,358,247) in view of Barcel et al. (U.S. Patent No. 5,267,564). Applicants respectfully traverse this rejection.

Applicants respectfully submit that claim 20 is allowable at least because it depends from an allowable independent claim. As described above, Applicants cannot find in Altman “removing material from an outer surface of the fixation helix to form at least one recess in the helix” in combination with the other elements required by claim 18. Barcel does not remedy the deficiencies of Altman.

In addition, Altman and Barcel neither alone nor in combination disclose each limitation of claim 20. For example, Applicants cannot find in Altman or Barcel “disposing a drug filled glass frit within the helix” as required by claim 20. Barcel describes “glass frit sealing rings” but Applicants cannot find any discussion in Barcel of “a drug filled glass frit” as recited by claim 20. Applicants are also unable to find in Barcel any discussion of disposing a drug filled glass frit “within the helix” as recited by claim 20.

Moreover, the Office Action does not supply an objective motivation to combine the references. According to the Office Action, “The use of glass frit is common in the art, as shown by Barcel, and would have been obvious to use with Altman due to its superior performance in implantable leads.” (Office Action, p. 3.) Applicants note that the Office Action fails to provide full objective support for this assertion, as required by Lee. For example, Applicants cannot find any discussion in Barcel of “superior performance” of glass frit in implantable leads. Applicants timely traverse the assertion under § 2144 and request that a proper reference be provided. Applicants also request an affidavit pursuant to § 2144.03 to support any facts within the personal knowledge of the examiner that are relied upon in making the rejection. Applicants respectfully submit that a legally sufficient motivation to combine the references has not been established.

In addition, Barcel teaches away from using a drug filled glass frit. Barcel describes “A hermetic seal is easily achieved by heating the glass frit such that the glass frit reflows between the end caps and the shell.” (Barcel Abstract.) In contrast, claim 20 recites “disposing a drug-

eluting substance within the at least one recess.” The creation of a hermetic seal described by Barcel conflicts with the drug-eluting quality recited in claim 20.

Reconsideration and withdrawal of the rejection of claim 20 is respectfully requested.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 10/671,009

Filing Date: September 25, 2003

Title: ACTIVE FIXATION ASSEMBLY FOR AN IMPLANTABLE DEVICE

Page 12
Dkt. 279.688US1

Conclusion

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 20 day of December, 2004.

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